



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Radiotherapy for metastatic castration-resistant prostate cancer.

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive commercialization patent license to Sinotau Pharmaceutical Group, headquartered in Beijing, China, to practice the inventions embodied in the patent application(s) listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Michael Shmilovich, Esq., Senior Licensing and Patent Manager, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479, phone number 301-435-5019, or shmilovm@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to Sinotau Pharmaceutical Group: U.S. Provisional Patent Application 62/633,648, “Chemical

Conjugates Of Evans Blue Derivatives And Their Use As Radiotherapy And Imaging Agents For Targeting Prostate Cancer,” filed February 22, 2018 (HHS Ref. No. E-054-2018-0). The patent rights in this invention have been assigned to the Government of the United States of America. The perspective license would be granted worldwide and in a field of use not broader than radiotherapeutics for metastatic castration-resistant prostate cancer.

The invention covered by the patents and patent applications pertaining to HHS Ref. No. E-054-2018-0 pertain to a therapeutic agent that includes a chemically conjugated residue derived from (((R)-1-carboxy-2-mercaptoethyl)carbamoyl)-L-glutamic acid that is further bound to an Evans blue analog (EB). The EB analog reversibly binds to circulating serum albumin to provide a radiopharmaceutical that retains affinity and specificity to prostate specific membrane antigen (PSMA; in this case PSMA-617). PSMA is a surface molecule shown to be specifically expressed by prostate tumor cells. PSMA expression levels correlate with disease stage and with hormone refractory cancers. Although most PSMA expression appears to be restricted to the prostate cancer, low levels of expression can also be detected in the brain, kidneys, salivary glands, and small intestine. The antigen is also shown to be expressed by neovascular tumor vessels of multiple other cancers. Inclusion of the Evans blue analog promotes high internalization and retention rates of the conjugated target ligand, and therefore, higher accumulation in PSMA positive tumors. Labeling EB-PSMA-617 derivatives with the therapeutic beta emitters, e.g., ^{90}Y , ^{86}Y , and ^{177}Lu gives rise to improved tumor response and survival rates.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive patent license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NHLBI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: July 19, 2018.

Michael A. Shmilovich,
Senior Licensing and Patenting Manager,
National Heart, Lung, and Blood Institute,
Office of Technology Transfer and Development.

[FR Doc. 2018-16066 Filed: 7/26/2018 8:45 am; Publication Date: 7/27/2018]